

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 152528-280	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2005/003787	International filing date (<i>day/month/year</i>) 04 March 2005 (04.03.2005)	Priority date (<i>day/month/year</i>) 04 March 2004 (04.03.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MEIJI SEIKA KAISHA, LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Date of issuance of this report 29 November 2006 (29.11.2006) Authorized officer <div style="text-align: center; font-weight: bold; font-size: 1.2em;">Masashi Honda</div> e-mail: pt08@wipo.int
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PATENT COOPERATION TREATY

TRANSLATION

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

152528-280

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/003787

International filing date (day/month/year)

04.03.2005

Priority date (day/month/year)

04.03.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

MEIJI SEIKA KAISHA, LTD.

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☒ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☒ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☐ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

The matter common to claims 1 to 9 and 10 to 12 resides in a β -fructofuranosidase mutant having a mutation in the amino acid sequence represented by SEQ ID NO:2.

As the result of a search, however, it was clarified that such a β -fructofuranosidase mutant having a mutation in the amino acid sequence represented by SEQ ID NO:2 is not novel because of having been disclosed in documents "WO 97/34004 A1 (Meiji Seika Kaisha, Ltd.), 18 September, 1997 (18.09.97) & EP 889134 A1 & US 2002/0192771 A1".

Therefore, this common matter falls within the category of the prior art and cannot be regarded as a special technical feature in the meaning within PCT Rule 13.2.

Such being the case, there is no special technical matter common to all the claims and the aforesaid invention groups cannot be considered as a group of inventions so linked as to form a single general inventive concept.

However, as all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☒ all parts
- ☐ the parts relating to claims Nos. _____

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-16</u>	YES
	Claims	_____	NO
Inventive step (IS)	Claims	_____	YES
	Claims	<u>1-16</u>	NO
Industrial applicability (IA)	Claims	<u>1-16</u>	YES
	Claims	_____	NO
2. Citations and explanations:			
<p>Document 1: WO, 97-34004, A1 (Meiji Seika Kaisha, Ltd.), 18 September, 1997(18.09.97), & EP, 889134, A1, & US, 2002-0192771, A1</p> <p>[Claims 1-16]</p> <p>The subject matters of claims 1-16 do not appear to involve an inventive step in view of document 1 cited in the ISR.</p> <p>Document 1 describes (1) a β-fructofuranosidase mutant derived from <i>Aspergillus niger</i> ACE-2-1(ATCC20611), (2) a DNA encoding the β-fructofuranosidase mutant, (3) an expression vector which comprises the DNA, (4) a host cell which comprises the expression vector, (5) a process for producing the β-fructofuranosidase mutant by cultivating the host cell, and (6) a process for producing a fructooligosaccharide comprising a step of bringing the β-fructofuranosidase mutant. Document 1 also describes (1) the mutant having the mutation in one amino acid residue (at positions 170, 300,313, or 386), (2) the mutant having the mutation in two amino acid residues (at positions 170+300, 300+313), and (3) the mutant having the mutation in three amino acid residues (at positions 170+300+313), as the β-fructofuranosidase mutant (see, claims 27-45, pages 46-66, and example D).</p> <p>Furthermore, document 1 also describes that (1) the characteristics of β-fructofuranosidase with its amino acid sequence, and (2) 1-kestose can be produced selectively and efficiently using the β-fructofuranosidase mutant (see, page 6, lines 3-6 and page 7, lines 10-17). Document 1 also describes that the mutant having three amino acid residues to be mutated can produce 1-kestose more selectively than the mutant having one amino acid residue (for example, see, examples D1 and D6).</p> <p>In addition, document 1 describes the amino acid sequences of the β-fructofuranosidase derived from <i>Aspergillus niger</i>, <i>Penicillium roqueforti</i> and <i>Scopulariopsis brevicaulis</i>, and the nucleotide sequence (see, SEQ ID No. 1, 2 and 11-14).</p> <p>Document 1 describes that (1) 1-kestose and nystose make up part of the industrially produced fructooligosaccharide mixtures of today, and (2) their high-purity crystals exhibit new desirable characteristics both in physical properties and food processing purpose while maintaining the general physiological advantages of fructooligosaccharides (see, page 4, lines 12-18).</p> <p>Considering that document 1 describes 1-kestose or nystose with high-purity has desirable characteristics, proposing to produce the 1-kestose or nystose with high-purity could have been easily conceived of. Furthermore, (1) creating a mutant by introducing a mutation randomly or site-specifically, (2) measuring desired characteristics, and (3) obtaining the mutant having the desired characteristics are well-known techniques to a person skilled in the art. So, when the 1-kestose or nystose with high-purity is produced, it is not considered to be especially difficult to (1) introduce a</p>			

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

mutation to the amino acid residues of the β -fructofuranosidase and (2) obtain a new mutant, in the process for producing the β -fructofuranosidase mutant described in document 1, and the effects of claims 1-16 could have been predicted from the description of document 1.

Moreover, document 1 describes that the mutant having three amino acid residues to be mutated can produce 1-kestose more selectively than the mutant having one amino acid residue, and judging from this description, producing the β -fructofuranosidase mutant having mutations in amino acid residues at three positions could have been, as required, carried out.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The invention of the present application relates to a β -fructofuranosidase mutant. Claims 1, 4 and 10 show a plurality of the positions of the amino acid residue having a mutation, and claims 3, 6, 9 and 12 also show a plurality of substituted amino acids. However, the specification merely specifically discloses (1) the β -fructofuranosidase mutant (G62E, L122M, I128N, V165F, H221Y, Q395L, T550S, G40D, T381M, and W379C) having one substitution and (2) the β -fructofuranosidase mutant (V165F+G300V+H313K) having three substitutions, in the amino acid sequence represented by SEQ ID No. 2. So, the Claims are not supported by the specification as a whole.